UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,284	08/09/2001	Daniel Hawiger	600-1-081 CON/CIP	2660

23565 7590 02/12/2004

KLAUBER & JACKSON
411 HACKENSACK AVENUE
HACKENSACK, NJ 07601

EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/925,284	HAWIGER ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) 1-5 and 10-12 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 6-9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 6-9 are under consideration. Claim 6 has been amended.

RESPONSE TO APPLICANTS ARGUMENTS

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 6-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the method of claim 6 wherein the limitation "and preventing maturation of said dendritic cell ex vivo or in vivo" has been removed. Regarding the specification, page 4, the cited passage refers to a method that recites "in combination with other factors or conditions, may lead to a more robust immune response to the preselected antigen, or tolerance to the preselected antigen", wherein said limitation is not recited in claim 6. Regarding the specification, page 14, the cited passage indicates that "Thus, without dendritic cell stimulation at the time of antigen presentation, tolerance to the delivered antigen rather than induction of a cellular response is achieved.". Thus, said method includes a step wherein the conjugate is administered in the absence of dendritic cell stimulation, wherein such a step is not recited in claim 6. The specification pages 17 and 18 also do not disclose the method of claim 6. There is no support in the specification as originally filed for the scope of the claimed invention (eg. the claimed invention constitutes new matter).

4. Regarding priority for the claimed invention and the application of prior art, the claimed invention is not disclosed in parent applications 09/586704 or 08/381528 for the same reasons that the claimed invention constitutes new matter as per paragraph 3 of this Office Action. In addition, the particular passages of the parent applications to which applicant refers do not provide support for the scope of the claimed invention. Regarding parent applications, page 7, said passage is limited to a description of a composition to "induce immune suppression" (immune suppression is not immune tolerance) with the proviso that the composition lacks immune stimulatory agents (limitation not currently in claim 6). Said passage further states that:
"By targeting an autoantigen or allergen to dendritic cells without including stimulatory agents, e.g. , cytokines, lymphokines, or adjuvants, the quiescent dendritic cells can process and present antigen. Presentation of antigen by quiescent dendritic cells is believed to induce antigen-specific T cell anergy or immune tolerance". Said passage is limited to autoantigens or allergens (limitation not in claim 6) and a method that recites "without including stimulatory agents". Thus, the cited passages do not provide support for the scope of the claimed invention. Therefore, regarding prior art the effective filing date of the instant application is the filing date of the instant application.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 6,7,9 are rejected under 35 U.S.C. 102(b) as being anticipated by Steinman et al. (WO 96/23882).

Steinman et al. disclose use of conjugate containing antiDEC 205 antibody and a protein antigen to induce tolerance to said antigen (see page 47, lines 6-14, page 7, lines 17-28). Steinman et al. disclose single chain antibodies which bind DEC 205 (see page 43, lines 12-19). Steinman et al. teach that the conjugate can be used to induce tolerance to autoantigens in autoimmune disease (see page 47). While the Steinman et

al. reference discloses the use of additional steps in the claimed method (eg. without including stimulatory agents), the claimed method is a method "comprising" and thus could include additional steps not currently recited in the claim under consideration.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 6-9 rejected under 35 U.S.C. 103(a) as being unpatentable over Steinman et al. (WO 96/23882) in view of Black et al. (US Patent 6,440,418 as applied to claims 6,7,9 above, and further in view of Siegall (US Patent 5,541,110).

Steinman et al. disclose use of conjugate containing antiDEC 205 antibody and a protein antigen to induce tolerance to said antigen (see page 47, lines 6-14, page 7, lines 17-28). Steinman et al. disclose single chain antibodies which bind DEC 205 (see page 43, lines 12-19). Steinman et al. teach that the conjugate can be used to induce tolerance to autoantigens in autoimmune disease (see page 47). While the Steinman et al. reference discloses the use of additional steps in the claimed method (eg. without including stimulatory agents), the claimed method is a method "comprising" and thus could include additional steps not currently recited in the claim under consideration.

Steinman et al. do not teach a linking agent to conjugate the protein and antiDEC 205 antibody. Siegall et al. teach use of cross linking agents to conjugate proteins to antibodies (see column 10, penultimate paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Steinman et al. teach the claimed method except for use of a cross linking agent to conjugate the protein and antiDEC 205 antibody whilst Siegall et al. teach use of cross linking agents to conjugate proteins to antibodies.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached Monday to Thursday from 7:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571 272-0851. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644